15.1 CONTROL OF NONCONFORMING ITEMS	Identifier: PRD-5086 Revision: 4 Page: **1** of 10

Companywide	Program Requirements Documents	For Additional Info: http://EDMS	Effective Date: 01/27/03

Manual: 13A – Quality and Requirements Management Program Documents

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1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for controlling *items* (see def.) that do not conform to specified requirements to prevent their inadvertent installation or use. See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to all company organizations, all items related to facility safety, reliability or operation; and all items that are determined to be *suspect/counterfeit items* (S/CI; see def.).

The requirements identified in this PRD are optional for the following items unless S/CIs are involved:

A. Operational deficiencies controlled by operation or maintenance deficiency tracking systems that are reworked as normal *corrective maintenance* (see def.) to meet existing design requirements.

B. Nonconforming items discovered while in an *in-process* (see def.) status under work *process* (see def.) control *procedures* (see def.) that are reworked within the scope of the work process control to meet existing design requirements.

C. Items not related to facility safety, reliability, or operation (drinking water and sewage systems; office heating, cooling, electrical, and lighting systems, etc.).

This PRD does not apply to nonconforming Specific Manufacturing Capability product materials.

3. RESPONSIBILITIES

3.1 Quality Assurance Organization

The quality assurance organization is responsible for establishing the procedure(s) for definition, implementation, and maintenance of the company's process for the control of nonconforming items.

3.2 Cognizant Director or Designee (Site-Area, Functional, and Program)

The cognizant director or designee is responsible for:

A. Ensuring company-level procedures relating to the nonconforming item process are effectively implemented.

B. Promoting an open environment and culture to support the identification and resolution of nonconforming items so that employees may report *nonconformances* (see def.) without fear of reprisal.

C. Ensuring that nonconforming items affecting the site-area, program or functional areas under their purview are identified, documented, and resolved in an effective and timely manner.

D. Using designees to implement many of the activities to resolve nonconforming items and to ensure that adequate priority and resources are allocated for effective process implementation.

E. Performing categorization and ensuring the completion of applicable reportability reviews and operability evaluations, as required, for nonconforming items.

F. Ensuring nonconforming items are properly tagged or segregated to prevent inadvertent installation or use.

G. Ensuring that nonconforming items that pose a threat to employee safety or health, or represents an imminent threat to the environment, the public or property are placed in a safe condition and that an evaluation is conducted to determine if stopping work is warranted.

3.3 Responsible Manager

The *responsible manager* (see def.) is responsible and accountable to the cognizant director for ensuring that:

A. Investigation and evaluation of nonconforming items are conducted to determine the disposition of nonconforming items.

B. Appropriate cause analysis is performed and documented by a qualified analyst.

C. Conditional use evaluations are done, if needed.

D. Appropriate engineering change control measures are implemented for nonconforming items that are under *configuration control* (see def.).

E. Corrective action plans address the identified cause, and that *technical justifications* (see def.) are documented for *use-as-is* or *repair* (see defs.) dispositions.

F. Corrective action plans are reviewed and approved, and implemented as scheduled, or rescheduled, as necessary, with approval from the cognizant director.

G. All necessary documentation supporting nonconforming item closure is maintained as a *quality assurance record* (see def.).

H. Appropriate *verification* (see def.) activities are performed.

I. Status of the nonconforming item in the Issue Communication and Resolution Environment (ICARE) tracking system is kept current.

3.4 Cognizant Quality Engineers

Cognizant Quality Engineers (see def.) are responsible for:

A. Reviewing and concurring with conditional use evaluations, nonconforming item dispositions.

B. Performing verification *inspections* (see def.) of *implemented corrective actions* (see def.).

C. Ensuring that quality nonconformance control status tags are applied and removed as appropriate.

3.5 Employees

Employees are responsible for identifying and reporting items that could be categorized as nonconforming.

3.6 Suspect/Counterfeit Items Subject Matter Expert

The S/CI *subject matter expert* (SME; see def.) is responsible for:

A. Evaluating items for suspect/counterfeit determination and providing for their disposition

B. Consulting with the Inspector General (IG) for the disposition of S/CI.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 Basic

4.1.1.1 Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use of the item. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to relevant organizations. *[NQA-1-1997, Requirement 15, 100 1s and 100 2s]*

4.1.2 Documentation and Evaluation

4.1.2.1 Nonconformance documentation shall clearly identify and describe the *characteristics* (see def.) that do not conform to specified criteria. *[DOE/RW-0333P 15.2.1.A]*

4.1.2.2 Nonconforming items shall be evaluated; and recommended dispositions shall be proposed, evaluated, and approved. *[NQA-1-1997, Requirement 15, 401 1s; DOE/RW-0333P 15.2.1.B.1s and 15.2.1.C]*

4.1.2.3 The review shall include determining the need for corrective action according to the requirements of PRD-5087, 16.1 Corrective Action. *[DOE/RW-0333P 15.2.1.B.2s]*

4.1.2.4 Documentation of a nonconformance in an NCR is required when an item *[Company Imposed Requirements]*:

A. Fails to meet required technical or quality requirements. *[Company Imposed Requirements]*

B. Is of indeterminate quality. *[Company Imposed Requirements]*

C. Is a suspect/counterfeit item. *[Company Imposed Requirements]*

D. Has documentation deficiencies (i.e., missing, incomplete, illegible, or damaged documents; improper revisions; or documents having unauthorized changes) which render the quality of the item indeterminate. *[Company Imposed Requirements]*

4.1.3 Notification

4.1.3.1 Organizations affected by the nonconformance shall be notified. *[DOE/RW-0333P 15.2.1.B.3s]*

4.1.4 Personnel

4.1.4.1 Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information. *[NQA-1-1997, Requirement 15, 403; DOE/RW-0333P 15.2.1.D]*

4.1.5 Responsibility and Authority

4.1.5.1 The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be defined. *[NQA-1-1997, Requirement 15, 402 1s; DOE/RW-0333P 15.2.1.E]*

4.1.5.2 Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing. *[NQA-1-1997, Requirement 15, 402 2s; DOE/RW-0333P 15.2.1.F]*

4.1.5.3 Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel. *[NQA-1-1997, Requirement 15, 401 2s; DOE/RW-0333P 15.2.1.F]*

4.1.6 Identification

4.1.6.1 Nonconforming items shall be identified by marking, tagging, or other methods not detrimental to the item, the container, or the package containing the item. The identification shall be legible and easily recognizable. *[NQA-1-1997, Requirement 15, 200; DOE/RW-0333P 15.2.2.A.1s and 15.2.2.A.2s]*

4.1.6.2 If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified. *[DOE/RW-0333P 15.2.2.B]*

4.1.7 Segregation

4.1.7.1 Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. *[NQA-1-1997, Requirement 15, 300 (a); DOE/RW-0333P 15.2.3.A]*

4.1.7.2 When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of the nonconforming item. *[NQA-1-1997, Requirement 15, 300 (b); DOE/RW-0333P 15.2.3.B]*

4.1.8 Disposition

4.1.8.1 The disposition of use-as-is, *reject* (see def.), repair, or *rework* (see def.) for nonconforming items shall be identified and documented. *[DOE/RW-0333P 15.2.4.A; NQA-1-1997, Requirement 15, 404 1s]*

4.1.8.2 The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use-as-is shall be documented. *[DOE/RW-0333P 15.2.4.B and 3.2.8.A; NQA-1-1997, Requirement 15, 404 2s]*

4.1.8.3 Items that do not meet original design requirements that are dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. *[DOE/RW-0333P 15.2.4.C; NQA-1-1997, Requirement 15, 404 3s]*

4.1.8.4 Required as-built records shall reflect the use-as-is or repair condition. *[NQA-1-1997, Requirement 15, 404 4s]*

4.1.8.5 If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance. *[DOE/RW-0333P 15.2.4.C.1]*

4.1.8.6 Any document or quality assurance record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation. *[DOE/RW-0333P 15.2.4.C.2]*

4.1.8.7 The disposition of an item to be reworked, or repaired shall contain a requirement to re-examine (inspect, *test [*see def.]), or nondestructively examine) the item to verify acceptability. *[DOE/RW-0333P 15.2.4.D.1s]*

4.1.9 Re-examination

4.1.9.1 Repaired or reworked items shall be reexamined using the original process and *acceptance criteria* (see def.) unless the nonconforming item disposition has established alternate acceptance criteria. *[NQA-1-1997, Requirement 15, 405; DOE/RW-0333P 15.2.4.D.2s]*

4.1.10 Quality Trending

4.1.10.1 Nonconformance documentation shall be periodically analyzed by the Quality Assurance organization to identify quality trends in accordance with PRD-5087, 16.1 Corrective Action. *[DOE/RW-0333P 15.2.5]*

4.1.11 Records

4.1.11.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. *[Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]*

5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

acceptance criteria

characteristic

cognizant quality engineer

configuration control

corrective action

corrective maintenance

in-process

inspection

item

nonconformance

procedure

process

quality assurance record

reject

repair

responsible manager

rework

subject matter expert

suspect/counterfeit item

technical justification

test

use-as-is

verification

6. REFERENCES

10 CFR 21, Reporting of Defects and Noncompliance

ASME NQA-1-1997, Quality Assurance Program Requirements for Nuclear Facilities

DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10

10 CFR 830 Subpart A, Quality Assurance

7. APPENDICES

Appendix A, 15.1 Basis

APPENDIX A

15.1 Basis

Source	Citation	Requirement	Comment
10 CFR 21, Reporting of Defects and Noncompliance	Summary of applicable requirements	0	CR
ASME NQA-1-1997, Quality Assurance Program Requirements for Nuclear Facilities, Requirement 15	100 1s and 100 2s	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 15	200	4.1.6.1	CR
NQA-1-1997, Requirement 15	300(a)	4.1.7.1	CR
NQA-1-1997, Requirement 15	300(b)	4.1.7.2	CR
NQA-1-1997, Requirement 15	401 1s	4.1.2.2	CR
NQA-1-1997, Requirement 15	401 2s	4.1.5.3	CR
NQA-1-1997, Requirement 15	402 1s	4.1.5.1	CR
NQA-1-1997, Requirement 15	402 2s	4.1.5.2	CR
NQA-1-1997, Requirement 15	403	4.1.4.1	CR
NQA-1-1997, Requirement 15	404 1s	4.1.8.1	CR
NQA-1-1997, Requirement 15	404 2s	4.1.8.2	CR
NQA-1-1997, Requirement 15	404 3s	4.1.8.3	CR
NQA-1-1997, Requirement 15	404 4s	4.1.8.4	CR
NQA-1-1997, Requirement 15	405	4.1.9.1	CR
Company Imposed Requirement	N/A	4.1.2.4.A	Company Imposed Requirement (CIR)
Company Imposed Requirement	N/A	4.1.2.4.B	CIR
Company Imposed Requirement	N/A	4.1.2.4.C	CIR
Company Imposed Requirement	N/A	4.1.2.4.D	CIR
Company Imposed Requirement (CIR)	N/A	4.1.2.4	CIR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	15.2.1.A	4.1.2.1	CR
DOE/RW-0333P	15.2.1.B.1s and 15.2.1.C	4.1.2.2	CR
DOE/RW-0333P	15.2.1.B.2s	4.1.2.3	CR
DOE/RW-0333P	15.2.1.B.3s	4.1.3.1	CR
DOE/RW-0333P	15.2.1.D	4.1.4.1	CR
DOE/RW-0333P	15.2.1.E	4.1.5.1	CR
DOE/RW-0333P	15.2.1.F	4.1.5.2	CR
DOE/RW-0333P	15.2.1.F	4.1.5.3	CR
DOE/RW-0333P	15.2.2.A.1s and 15.2.2.A.2s	4.1.6.1	CR
DOE/RW-0333P	15.2.2.B	4.1.6.2	CR
DOE/RW-0333P	15.2.3.A	4.1.7.1	CR
DOE/RW-0333P	15.2.3.B	4.1.7.2	CR

APPENDIX A

15.1 Basis

Source	Citation	Requirement	Comment
DOE/RW-0333P	15.2.4.A	4.1.8.1	CR
DOE/RW-0333P	15.2.4.B and 3.2.8.A	4.1.8.2	CR
DOE/RW-0333P	15.2.4.C	4.1.8.3	CR
DOE/RW-0333P	15.2.4.C.1	4.1.8.5	CR
DOE/RW-0333P	15.2.4.C.2	4.1.8.6	CR
DOE/RW-0333P	15.2.4.D.1s	4.1.8.7	CR
DOE/RW-0333P	15.2.4.D.2s	4.1.9.1	CR
DOE/RW-0333P	15.2.5	4.1.10.1	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.11	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and company imposed requirements